ROUND OR ANATOMICAL TYPE SILICONE PROSTHESIS HAVING SHELL WITH ENHANCED DURABILITY AND METHOD FOR MANUFACTURING SAME

REFERENCE TO RELATED APPLICATIONS

This is a continuation of pending International Patent Application PCT/KR2011/006780 filed on Sep. 14, 2011, which designates the United States and claims priority of Korean Patent Application No. 10-2010-0093850 filed on Sep. 28, 2010, Korean Patent Application No. 10-2011-0030363 filed on Apr. 1, 2011, and Korean Patent Application No. 10-2011-0082393 filed on Aug. 18, 2011, the entire contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to a round or anatomical type silicone prosthesis including a shell having enhanced durability and a method for manufacturing the same, and more particularly to a round or anatomical type silicone prosthesis including a shell having enhanced durability, which is manufactured such that the shell of the silicone prosthesis having a smoothly curved surface at a front side thereof is formed thin and to a constant thickness whereby the silicone prosthesis has superior texture and functions well in the body, removes differences in the thickness of the shell of the silicone prosthesis which determines the entire strength of the silicone prosthesis to minimize stress concentration after extensive use, and increases resistance to fatigue fracture to maximize safety and lifespan of the silicon prosthesis, and a method for manufacturing the same.

BACKGROUND OF THE INVENTION

In general, silicone prostheses are inserted into the human body for various purposes such as plastic surgery, and the like. As a representative example, artificial breast prostheses are used in reconstructive surgery when breast loss occurs due to diseases or accidents and in cosmetic surgery to treat a malformed breast. In terms of anatomy, artificial breast prostheses are also used for the substitution of organs or tissues.

Artificial breast prostheses are products in which a sufficient amount of a filling material, such as saline, hydro-gel, and silicone gel, is filled in an envelope formed of silicone that can be used to manufacture artificial organs (hereinafter, referred to as a "shell"), which are devices for substitution of organs in the body. These artificial breast prostheses may be classified into products according to filling materials contained therein, may be classified into round type products and anatomical type products, which are of water droplet type, according to the shape of a product, and may be classified into smooth products and textured products according to surface condition.

For example, a saline filled artificial breast prosthesis is configured such that saline is injected or is injectable into a shell formed of silicone (e.g., polydimethylsiloxane (PDMS), polydiphenylsiloxane, and polyorganosiloxane). The saline filled artificial breast prosthesis has a structure consisting of a silicone shell and a valve.

Although the saline filled artificial breast prosthesis ensures user safety even if the filling material leaks into the human body after rupture of the shell as a result of using sterile saline as the filling material, and is easy to change the volume of a breast by adjusting the injection amount of saline, the saline filled artificial breast prosthesis is significantly deteriorated to the touch after surgery as compared to other artificial breast prostheses and the shell thereof has inferior durability.

A hydro-gel filled artificial breast prosthesis is configured such that hydro-gel composed of monosaccharide and polysaccharides is filled within the shell as in the above-described saline filled artificial breast prosthesis. The hydro-gel filled artificial breast prosthesis was developed based on the principle that the filling material can be absorbed into and excreted from the human body even if the filling material leaks due to rupture of the prosthesis.

However, in the case of the hydro-gel filled artificial breast prosthesis, long-term safety has not been established, volume change over time and occurrence of wrinkles may increase after the artificial breast prosthesis is implanted, and feeling is unnatural as compared to a silicone artificial breast prosthesis. Accordingly, the hydro-gel filled artificial breast prosthesis is not currently distributed in the market as safety thereof has yet to be proven.

A silicone gel filled artificial breast prosthesis is configured such that a shell is filled with a silicone gel having an appropriate viscosity. The silicone gel filled artificial breast prosthesis has superior product durability and a more pleasant texture than the saline filled artificial breast prosthesis and thus achieves a dominant position in the market. Although the Food and Drug Administration of the United States of America (FDA) has imposed limitations on use of silicone gel filled artificial breast prostheses due to safety issues, the use of silicone gel filled artificial breast prostheses was again allowed officially in 2006.

The silicone gel filled artificial breast prosthesis has been developed in the order of a first generation prosthesis, a second generation prosthesis, and a third generation prosthesis. This development history will be described in detail as follows.

The first generation silicone gel filled artificial breast prosthesis is a product sold from the middle of the 1960s to the middle of the 1970s, and was initially developed in 1961 by Cronin and Gerow. The first generation silicone gel filled artificial breast prosthesis can be represented in brief by the use of a thick shell, a smooth surface, and a high viscosity silicone gel. This prosthesis suffers from gel bleed and capsular contracture, but a rupture speed thereof is relatively low due to the use of the thick shell.

The second generation silicone gel filled artificial breast prosthesis is a product sold from the middle of the 1970s to the middle of the 1980s, and includes a thin shell and a silicone gel filling material of a low viscosity, for the sake of smoother texture. This prosthesis is characterized by a similar gel bleed rate, higher rupture occurrence, and lower capsular contracture as compared to the first generation prosthesis.

The third generation silicone gel filled artificial breast prosthesis is a product sold from the middle of the 1980s to the present, and includes a gel bleed barrier layer to prevent gel bleed. The third generation silicone gel filled artificial breast prosthesis includes a thicker shell and silicone gel of a higher viscosity as compared to the second generation prosthesis. In addition, a product having a rough surface has been developed, in order to reduce capsular contracture.

The above-described artificial breast prostheses commonly include a shell **1**, a filling material **2**, and a patch bonding portion (hereinafter, referred to as "patch portion **6**").

The shell **1** constituting a conventional artificial breast prosthesis is generally prepared using a dipping method or a spray method. When the shell **1** is prepared by dipping or spraying, silicone liquid is continuously flowed downward due to gravity in a drying process after dipping a mold in a